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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/813,998	03/30/2004	Edward J. Ellis	VIS-0008-P2	6070		
76808	7590	01/09/2009	EXAMINER			
Leason Ellis LLP			AUDET, MAURY A			
81 Main Street			ART UNIT			
Suite 100			PAPER NUMBER			
White Plains, NY 10601			1654			
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/813,998	ELLIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 June 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12 and 17-23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

Applicant's amendment and response are acknowledged. Due to Applicant's amendment to add casein as the macropeptide of choice for the ophthalmic preparations, to which the Examiner has found art in the updated search specific thereto, Applicant's arguments are deemed moot and not addressed.

***Election/Restrictions***

As noted previously, Applicant's election without traverse of Group I, claims 1-12 and 17-23, as drawn to any species of a glycoprotein, in the reply filed on 08/23/2006 is acknowledged. Claims 3-10, and 13-16 are withdrawn as being drawn to non-elected subject matter. Claims 1-12 and 17-23 are examined on the merits as drawn to any species of a glycoprotein (Applicant was telephoned to elect a specific glycoprotein, as required by restriction, but no return call was ever received).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 17-23 are rejected under 35 U.S.C. 103(a) as being obvious over Kee et al. (US 5,369,095, priority date of 3/12/93) in view of any of Kaufman (US 4,923,699), Leahy I

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et al. (US 6,281,192 B1), Leahy II et al. (US 6,429,194 B1)(collectively discussed under Leahy I et al.), or Hayashi (US 5,145,680) in view of Ogawa et al. (US 5,830913).

Kee et al. teach:

“The use of substituted glycosides to enhance the penetration of drugs across mucus covered epithelial tissues of humans and animals is disclosed, including enhanced penetrations of topically applied ophthalmic drugs through the corneal epithelium of said humans and animals (abstract)....In addition, proteins, synthetic polypeptides and polymer-peptide copolymers which enhance viscosity and are ophthalmically acceptable can be used to increase the viscosity of the compositions to provide for better bioavailability. Typically, proteins which can be used include: gelatin, collagen, albumin and casein.” (col. 6, lines 3-9; as well as entire document).

Kaufman teaches an ophthalmic preparation comprising a glycoprotein (mucin) for e.g. dry eye, that is inherently derived from whey, is inherently autoclavable (the latter two inherency's evidenced by the Leahy et al. references below), includes a buffering agent such as a carrier, and may be used in a container (col. 10, line 60-68; col. 11).

Leahy I and II et al. teach an ophthalmic preparation comprising a glycoprotein (e.g. mucin) for the treatment of dry eye (col. 1, line 57; claim 25), which may be derived from dairy whey (col. 7, line 32; claim 16), is autoclavable (claim 21), and further comprises an option for any of viscosifiers, buffering agents, tonicity agents, humectants, wetting agents, or other therapeutic drugs (col. 8, claims 10-15).

Hayashi teaches an ophthalmic preparation comprising a glycoprotein (Vitronectin), that is autoclavable, and may further comprise e.g. a buffer, (col. 1, line 42; claim 2; col. 2, line 18). Hayashi teach the use of a known glycoprotein. Since it is not known it the glycoprotein in Hayashi is also referred to as glycomacroproteins (or capable of the latter, depending on the isolated form or preference, or how the latter is defined, see 112 2<sup>nd</sup> rejection); the claims have

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nevertheless been rejected under 103 (as opposed to 102). However, the reference does not expressly teach a therapeutic package, with the specific labeling or specific amounts of administration in the form of %'s or "ml" (as opposed to percents of compounds therein) (Applicant's claims 17-23). [It is noted that the forms from which the glycomacroproteins may be derived (dairy whey, casein, sweet whey, purified whey, e.g. claims 2-3, and 11-12), as well as the Dalton size are deemed inherent properties of such glycoproteins/macroproteins, absent evidence to the contrary.] [It is also noted that Hayashi does not teach or render obvious claim 2, as the glycoprotein therein, is not isolated from dairy whey, casein, sweet whey, or purified whey, but rather from serum].

The references teach the use of known glycoproteins. Since it is not known if they are also referred to as glycomacroproteins (or capable of the latter, depending on the isolated form or preference, or how the latter is defined, see 112 2<sup>nd</sup> rejection); the claims have nevertheless been rejected under 103 (as opposed to 102). However, the references do not expressly teach a therapeutic package, with the specific labeling or specific amounts of administration in the form of %'s or "ml" (as opposed to percents of compounds therein) (Applicant's claims 17-23). . [It is noted that the forms from which the glycomacroproteins may be derived (dairy whey, casein, sweet whey, purified whey, e.g. claims 2-3, and 11-12), as well as the Dalton size are deemed inherent properties of such glycoproteins/macroproteins, absent evidence to the contrary.]

Ogawa et al. (merely cited by example in the art of known kits/products/labels for such preparations) teach an ophthalmic preparation for the treatment of dry eye comprising a container and labeling (title, col. 3, lines 35-57; col. 7, lines 24-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate an ophthalmic preparation comprising casein and any other ophthalmic additives (or using any other glycomacroprotein (if not inherent therein)) in Kee et al., since Kee et al. expressly teach the use of casein as a preferred glycomacropeptide for use in the same, either alone or in further view of any of within packages with labels directed to specific patients likely to use the same, and specific amounts thereof in the form of “ml” in any of Kaufman, or Leahy I or II et al, because Ogawa et al. advantageously teach dry eye formulations within packages/containers with instructive labeling, and the selection of “ml” as opposed to %’s for the directed amount of use is merely a matter of routine optimization by pharmacist in the dry eye field, depending on the choice of amount labeling (e.g. percents therein or “ml” of the active compound).

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate an ophthalmic preparation comprising a glycoprotein, within packages with labels directed to specific patients likely to use the same, and specific amounts thereof in the form of “ml” in Kee et al., based on Hayashi, because Ogawa et al. advantageously teach dry eye formulations within packages/containers with instructive labeling, and the selection of “ml” as opposed to %’s for the directed amount of use is merely a matter of routine optimization by pharmacist in the dry eye field, depending on the choice of amount labeling (e.g. percents therein or “ml” of the active compound).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

The applied references under Leahy I and Leahy II have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,281,192 B1 and claims 1-21 of U.S. Patent No. 6,429,194 B1 (collectively discussed under Leahy I et al.), in view of Kee et al. (US 5,369,095). Although the conflicting claims are not identical, they are not patentably distinct from each other because although neither expressly refer to mucin as a glycopeptide (which it is), both the '192 and '194 patents both teach an ophthalmic preparation comprising a glycoprotein (e.g. mucin) (and obvious to use a glycomacroprotein of the same, if not inherent therein) for the treatment of dry eye (claim 25), which may be derived from e.g. dairy whey (claim 16) or other known milk products, etc., is autoclavable (claim 21), and further comprises an option for any of viscosifiers, buffering agents, tonicity agents, humectants, wetting agents, or other therapeutic drugs (claims 10-15) -- in view of Kee et al., for the same reasons noted above under 103.

Claims 1-12 and 17-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 11-12, and 19-26 of copending Application No. US 10/814,001, in view of Kee et al. (US 5,369,095). Although the conflicting claims are not identical, they are not patentably distinct from each other because the only minor differences of the claims of '001 are that the glycomacroproteins are claimed as glycoproteins (which are deemed to be the same or merely smaller versions of the same proteins useable in the invention), and there is an option for the protein to be derived from dairy whey (or obvious from some other form of milk byproduct, like dairy whey), and the variation in form of amount claiming (e.g. %'s herein), is deemed a mere obvious alternative form, absent evidence to the contrary – in view of Kee et al., for the same reasons noted above under 103.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 1/2/2008

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654